Response to Claim Objections

1. (Currently amended) A collection vessel for collecting and transferring a body fluid specimen comprising: a hollow body having a first end and a second end;

a first seal at said first end;

a plunger disposed within said hollow body between said first end and said second end;

said plunger providing a second seal;

a plunger lock coupled to said plunger;

said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said hollow body between said first seal and said second seal is at least partially evacuated;

said plunger lock ~~can~~ further ~~be~~ configured to release said plunger, thereby allowing said plunger to move toward said first seal within said hollow body.

3. (Currently amended) A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of: providing a fluid collection needle having a first end and a second end;

providing a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end, said sterile seal configured wherein said sterile seal is maintained at said open end when at least a portion of said sterile hollow body is at least partially evacuated;

providing a device for collecting a second body fluid specimen comprising a sterile hollow body having and a closed end, a sterile seal at said open end, said sterile seal

configured wherein said sterile seal is maintained at said open end when at least a portion of said sterile hollow body is at least partially evacuated;

providing an antiseptic;

preparing a site on a patient's skin for puncture using said antiseptic; piercing said ~~puncture~~ site using said first end of said fluid collection needle;

at least partially filling said sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said fluid collection needle such that piercing through said sterile seal of said sterile evacuated specimen tube does not contaminate said second end of said fluid collection needle;

at least partially filling said device for collecting the second body fluid specimen with said second body fluid specimen having fewer living contaminants than said first body fluid specimen by piercing through said sterile seal of said device for collecting said second body fluid specimen using said second end of said fluid collection needle, such that piercing through said sterile seal of said device for collecting said second body fluid specimen does not contaminate said second end of said fluid collection needle and;

selecting said second body fluid specimen for use in a diagnostic test to detect the presence of organisms in said second body fluid specimen.

5. The rejection of claims 9, 13, and 16 of application 10/055,290 under 35 U.S.C 102(b) is being argued against as follows:

Distinction from Theodore A. Golden's patent number 4,676,256

Claims 9 and 13 of application 10/055,290 describe a method for collecting a first and a second body fluid specimen such that the second body fluid specimen has a lower concentration of living contaminants than the first body fluid specimen, using a fluid collection needle having a first and a second end, a sterile evacuated specimen tube, and a device for collecting a second body fluid specimen. This method was developed in order to allow the collection of at least the second body fluid specimen, and likely a third subsequent body fluid specimen, in a manner that makes it more suitable for a diagnostic test for the detection of the presence of microorganisms than what is provided by methods of the prior art.

The described manufactures and method of claims 9 and 13 accomplish this by controlling three key variables. First, contaminant material passing into the first end of the fluid collection needle upon venepuncture, comprising mainly skin and commensal microorganisms, is collected into the sterile evacuated specimen tube along with the first body fluid specimen. Second, the second end of the fluid collection needle avoids contamination from the sterile evacuated specimen tube due to the sterile state of the seal maintained at the open end of the sterile evacuated specimen tube. Third, the second end of the fluid collection needle avoids contamination from the device for collecting a second body fluid specimen due to the sterile state of the sterile seal maintained at the open end of the device. This third control prevents not only the contamination of the second body fluid specimen as the second end of the fluid collection needle passes through the sterile seal of the device for collecting a second body fluid specimen, but also maintains the sterile state of the second end of the fluid collection needle in order that an additional third body fluid specimen or plurality of body fluid specimens having a lower

concentration of contaminants than the first body fluid specimen can be further collected. It is only when all three variables are controlled that the second body fluid specimen is made more suitable for a diagnostic test for the presence of microorganisms than the first body fluid specimen.

The devices described in Golden's patent 4,676,256 comprise a hypodermic needle having an end to be "inserted into a patient's vein" and a plurality of upstanding needles oriented such that "downward movement of the vacuum tube also displaces or pushes the resilient plug downwardly toward the bottom of the socket, thereby permitting blood to flow into the vacuum tube through the upstanding needle." In studying the specifications of Golden's patent 4,676,256, it does appear reasonable that the described devices could be used in order to prevent contamination between collected blood samples. In this case, a method for collecting a first and a second body fluid specimen such that the second body fluid specimen has a lower concentration of contaminants than the first body fluid specimen, could avoid the need for the sterile seal on the sterile evacuated specimen tube if the first and the second body fluid specimens are collected on separate upstanding needles. However, if Golden's patent 4,676,256 is implemented in order to collect the first and the second body fluid specimen without further instruction, it remains equally likely that either body fluid specimen would be used in a diagnostic test for the detection of the presence of microorganisms. Thus, the first body fluid specimen having a higher concentration of living contaminants would be used in a diagnostic test for the detection of the presence of microorganisms as often as the second body fluid specimen, which is more suitable for such testing.

When combined with the teachings of the prior art, the situation is dramatically worsened. In the field of blood collection, the standard set forth by the National Committee for Clinical Laboratory Standards (NCCLS) for collecting blood specimens for culturing using a mutliple-sampling needle having a first and a second end dictates that a blood specimen for culturing be drawn before any other blood specimen as this is perceived as the most suitable blood specimen for culturing [1]. This standard is universally endorsed by other authorities in the field such as the Center for Phlebotomy Education (CPE) and the American Society for Phlebotomy Technicians (ASPT). Many health care providers have readily adopted this standard as policy [2,3,4,5,6], and there is no known deviation from this standard in practice. If Golden's patent 4,676,256 is implemented with the teachings of the prior art, it is very likely that the standard would remain intact for these devices as well. Thus, the first blood specimen using Golden's devices would more likely be the blood specimen selected for culturing when used by one skilled in the art.

Claims 9 and 13 of application 10/055,290 absolutely require that the first body fluid specimen be collected prior to the collection of the second body fluid specimen in order to prevent the entry of venepucture-derived contaminants into the second body fluid specimen. Additionally, in the prior art, with or without Golden's patent 4,676,256, when the only blood specimen needed for testing is the blood specimen for culturing no other blood specimens are collected. When claims 9 and 13 of application 10/055,290 are implemented in the collection of blood specimens for culturing, collection of a first blood specimen prior to a second blood specimen for culturing is necessary. This is in direct

opposition to the prior art and is believed to be unanticipated by Golden's patent 4,676,256.

Claim 16 of application 10/055,290 describes a kit that facilitates the execution of the methods of claims 9 and 13. The kit of claim 16 allows the sterile evacuated tube for collecting the first body fluid specimen and the device for collecting the second body fluid to be packaged such that the sterile evacuated tube and the device for collecting the second body fluid specimen maintain sterility on their external surfaces. This sterility is necessary in order to prevent contamination of the second end of the fluid collection needle when the sterile evacuated specimen tube and the device for collecting the second body fluid specimen are used as is described in claims 9 and 13. The kit of claim 16 also ensures that the sterile specimen tube and the device for collecting the second body fluid specimen are used together in a method consistent with claims 9 and 13. Golden's patent 4,676,256 does not appear to describe or anticipate the assembly of such a kit, nor does it suggest a method for using the contents of the kit.

7. The rejection of claims 10 and 11 of application 10/055,290 under 35 U.S.C 103(a) is being argued against as follows:

Claims 10 and 11 are claims dependent on the method for collecting a first and a second body fluid specimen, the second body fluid specimen having a lower concentration of living contaminants than the first body fluid specimen claimed in claim 9. Claim 9 requires that the second body fluid specimen be used in a diagnostic test for the detection of the presence of organisms. One of the diagnostic tests best known in the current art for detecting the presence of organisms is a blood culture. In the current art,

the blood culture requires a blood specimen that is directly drawn directly into a blood culture bottle, collected into an evacuated specimen tube having an additive of sodium polyanethole sulfonate (SPS), or collected into a syringe. In the latter two methods, the blood sample must be further transferred into the blood culture bottle for testing. Claims 10 and 11 claim the blood culture bottle and the specimen tube having a SPS additive as a device for collecting a second body fluid specimen within the limits of their use in the method of claim 9.

While it is agreed that it is obvious that Golden's patent 4,676,256 could be implemented in order to collect a blood sample into a blood culture bottle or an evacuated specimen tube having an SPS additive, it is believed that one skilled in the art would consistently choose to collect a first blood sample into the blood culture bottle or the evacuated specimen tube having an SPS additive. The reasoning upon which this prediction is based is described in point 5 of this response to office actions on application 10/055,290.